REMARKS

Applicants have canceled certain claims and have amended other claims to address certain objections and rejections set forth in the Office Action dated 24 October 2008. Applicants also provide below arguments in support of patentability of the claims over the prior art of record. Also addressed below are other alleged deficiencies set forth in the Office Action.

I. Drawings Stand Objected To Under 37 C.F.R. §1.84 And 37 C.F.R. §1.121

In section 2 of the Office Action, the drawings were objected to as failing to comply with 37 C.F.R. §1.84(p)(5) because they include in Fig. 4F the reference character 200n, which is not mentioned in the description.

In response, Applicants submit a replacement sheet for Fig. 4F wherein reference character 200n has been replaced with reference character 200. The replacement sheet thus corrects a typographical error made in the original drawing sheet. The term "Replacement Sheet" has been placed in the top margin as required by 37 C.F.R. §121(d). Applicants believe that the replacement sheet submitted herewith overcomes this objection and respectfully asks that it be withdrawn.

II. Claims 7, 10, 51, 54 And 66 Stand Objected To Under 37 C.F.R. §1.75(c)

In section 3 of the Office Action, dependent claims 7, 10, 51, 54 and 66 were objected to under 37 C.F.R.§1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

In response, Applicants have amended the claims herein to address the improper dependent forms and thereby overcome this objection.

III. Claims 27, 28, 61 And 62 Stand Objected To Due To Informalities

In sections 4 and 5 of the Office Action, dependent claims 27, 28, 61 and 62 were objected to because of informalities.

In response, Applicants have amended the claims herein to address these informalities and thereby overcome this objection.

IV. Claims 78, 79 81 And 83 Stand Rejected Under 35 U.S.C. §102(b)

In sections 7-11 of the Office Action, claims 78, 79, 81 and 83 were rejected under 35 U.S.C. §102(b) as being anticipated by the *Stevens et al.* patent.

In response, Applicants have canceled claims 78-83 thereby rendering this rejection moot.

V. Claims 63, 64, 65, 66 And 67 Stand Rejected Under 35 U.S.C. §103(a)

In sections 13-18 of the Office Action, claims 63, 64, 65, 66 and 67 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Lindsay* patent in view of the *Stevens et al.* patent.

Applicants respectfully submit that independent claim 63 and its dependents 64-67 are patentable over these references, and were so even before the amendments made herein to these claims. The teachings of the two cited references support this assertion.

The *Lindsay* patent discloses an aortic cannula 20, which is specialized tubing used to return blood to the aorta of a patient while the heart is bypassed during heart surgery. At the distal end 24, the cannula 20 has a tip 30 that is designed to be inserted through an incision in the wall of the aorta. (col. 2, lines 36-42) Blood pumped from a bypass machine is routed into and through the lumen 26 of cannula 20 and emerges from tip 30 into the aorta from which it flows to the rest of the body. The tip 30 has an annular cap 34 in which is defined a central opening 36 in direct communication with lumen

26. Figure 6 shows that opening 36 is contained within a "diffuser 38, for example a cone 40." (col.2, lines 50-52) The purpose of the frustoconically shaped diffuser 38 is "to gently diffuse [blood] radially outwardly" as it flows from lumen 26 through diffuser 38 of tip 30 into the aorta., as best shown in Figure 6. (col. 2, lines 52-56) In addition, helical slits 42 are cut into the flexible sidewall of tip 30, as best shown in Figures 6-9. (col. 2, line 56 – col. 3, line 6) As blood flows distally in lumen 26, it flows not only through diffuser 38 distally "to gently diffuse at least a portion of the flow ... radially outwardly" into the aorta but also through the slits 42 as well. In fact, as the pressure increases within lumen 26, the slits 42 open further as shown in Figures 7-9 progressively. The slits 42 actually widen in proportion to the pressure in lumen 26, thereby avoiding high pressure buildup in the tip 30. (col. 3, line 43 – col. 4, line 10)

Particularly as amended above, independent claim 63 recites a catheter assembly whose restrictor is distinctly different from the diffuser 38 of *Lindsay*. The claimed restrictor includes a circular base portion at its distal end. More importantly, as amended, it also includes a *flexible* conical wall portion that extends in a proximal direction from the circular base portion to an apex thereof whereat an opening is defined. As recited in claim 63, as pressure of the fluid within the restrictor increases (as fluid flows through the lumen distally), the increasing pressure causes the *flexible* conical wall portion to flatten out distally in response thereto. Consequently, due to the flexibility of the conical wall portion, the size of the opening at the apex of the conical wall portion decreases –the conical wall portion flattens out-- as the pressure within the restrictor increases.

The diffuser 38 of *Lindsay*, in contrast, does not flatten out distally in response to an increase in pressure within tip 30. In fact, *Lindsay* explicitly teaches that "high pressure buildup [in the tip 30]" is avoided because the "slits 42 [in the sidewall of tip 30] widen in proportion to the applied pressure" to allow the blood to flow therethrough into the aorta. (col. 4, lines 6-10) The rigidity of diffuser 38 is further bolstered by the *Lindsay* patent in that only the sidewall of tip 30 is taught as being flexible [to

allow the unwinding/opening of helical slits 42]." (col. 2, lines 56-57; col. 4, lines 50-60) The diffuser 38 of *Lindsay* is thus markedly different than the restrictor of claims 63-67 as the former is not only rigid but also prevents pressure buildup therein beyond a set threshold because helical/spiral slits 42 unwind/open in response to the pressure and thus allow blood to flow therethrough into the aorta.

The *Stevens et al.* patent discloses a flow directed venting catheter 620 for use on a patient undergoing a cardiopulmonary bypass procedure. This catheter is used to vent blood from the heart while the heart is stopped and the patient is on cardiopulmonary bypass. The catheter 620 features at its distal end a balloon 634, which can be inflated (deflated) by passing (evacuating) an inflation medium through a delivery lumen 626, an inflation lumen 640 and an inflation port 642, as best shown in Figures 4H & 4J. In use, the catheter 620 is introduced into a peripheral vein and then eventually advanced through the vena cava into the right atrium of the heart. The balloon 634 is then inflated. Under the guidance of the physician, the flow of blood then tends to carry the balloon 634 and the distal end 636 of catheter 620 therewith through the tricuspid valve into the right ventricle, and from that ventricle through the pulmonary valve into the pulmonary artery. (col. 14, lines 27-39)

The *Stevens et al.* catheter 620 also features a one-way valve 660 in delivery lumen 626, as best shown in Figs. 4H & 4J. The valve 660 has a plurality of pie-shaped leaflets 662. (col. 14, lines 56-57) The valve 660 is configured so that its leaflets 662 are closed/sealed in the closed position when the balloon 634 is being inflated via delivery lumen 626. (col. 14, line 61 – col. 15, line 1) With the distal end 636 of catheter 620 positioned in the pulmonary artery, the lumens 626 & 640, and inflation port 642 can be evacuated and balloon 634 deflated. Blood from the pulmonary artery can then be withdrawn through the one-way valve 660, as the force of the flow of blood opens leaflets 662, and the blood removed from the body for oxygenation and then returned to the body as part of the cardiopulmonary bypass procedure. (col. 14, lines 27-39; col. 44, lines 1-36)

Claim 63 as amended recites a catheter assembly whose restrictor is patentably distinct over the combination of the *Lindsay* and *Stevens et al.* patents. As noted above, the diffuser 38 of *Lindsay* is rigid and thus its opening 36 does not decrease in size --flatten out distally-- as pressure in the diffuser increases, as the Office Action acknowledges in section 14. As for the *Stevens et al.* patent, the valve 660 does not have a *flexible* conical wall portion (or even a rigid one), only several individual and separate pie-shaped leaflets 662. In fact, at best, the leaflets 662 form a cone shape only when fully closed. When open, the leaflets 662 cannot form a cone-shape at all, as they are by definition separated from each other. In contrast, the conical wall portion of claims 63-67 always remains an inseparable or indivisible structure. Furthermore, unlike the restrictor of claims 63-67, the valve 660 of *Stevens et al.* must occupy either the closed or open position and no state in between. (The leaflets 662 must be closed during inflation of balloon 634 to prevent air from being injected into the pulmonary artery and thus to avoid causing air embolism, a potentially lethal condition. Conversely, the leaflets 62 must be open when blood is withdrawn through valve 660 from the pulmonary artery during the cardiopulmonary bypass procedure.) The language of claims 63-67, however, clearly conveys the point that the size of the opening is changeable from being larger to smaller as the pressure within the restrictor increases (i.e., the "conical wall portion ... defin[es] an opening whose size generally decreases as said ... valve flattens out distally as pressure of the fluid within the restrictor increases"). Consequently, unlike the valve 660 of *Stevens et al.*, the size of the opening in Applicants' claims ranges from a largest size to a smallest size and every size in between depending on the amount of pressure built up within the restrictor.

For the foregoing reasons, Applicants believe that claims 63-67 are not rendered obvious by the combination of the *Lindsay* and *Stevens et al.* patents. Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejections of the cited claims.

VI. Claims 1-3, 6-18, 22, 24-25, 29-32, 37-40, 46-47, 50-59 & 68-73 Rejected-35 U.S.C. §103(a)

In sections 19-46 of the Office Action, claims 1-3, 6-18, 22, 24, 25, 29-32, 37-40, 46, 47, 50-59 and 68-73 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the *Lindsay* patent in view of the *Stevens et al.* patent and the *Savage et al.* publication. In this group of rejected claims, the independent claims are 1, 29 and 70.

Applicants respectfully submit that independent claims 1, 29 and 70 and their respective dependents are patentable over the *Lindsay* and *Stevens et al.* patents for the reasons set forth in the previous section, and for that reason the arguments therein are incorporated herein by reference. To reiterate only briefly, the diffuser 38 of *Lindsay* is not a valve at all, merely a mechanism to diffuse a portion of the distally-directed blood flow radially outwardly into the aorta. Because diffuser 38 is rigid, its opening 36 does not flatten out distally (i.e., decrease in size) as pressure in the diffuser increases, as the Office Action acknowledges in section 20. In the *Stevens et al.* patent, the valve 660 forms a cone shape only when its separate leaflets 642 are fully closed. The conically shaped valve of claims 1 and 29, however, always remains an inseparable or indivisible structure, as it has no such leaflets. Furthermore, unlike the conically shaped valve of claims 1 and 29, and the restrictor of claim 70, the valve of *Stevens et al.* can only occupy the closed position or open position and no position therebetween for the reasons noted above. The language of claims 1, 29 and 70, however, allows the size of the opening to range from large to small and every size in between depending on the amount of pressure built up within the tip of claims 1 and 29 or within the restrictor of claim 70.

As for the *Savage et al.* publication, this publication discloses a catheter having a small number of sideholes 42 angled in the proximal direction along with an elastic opening 44 in its distal end that allows passage of a guidewire. The sideholes 42 are made via a punching process, which is responsible for their large diameter (0.254 mm and larger). (p. 11, lines 32-34) Consequently, they are not microholes of the size claimed by Applicants. More importantly, *Savage et al.* assert that their

catheter balances the forces acting upon it by (i) restricting the flow of fluid through the opening 44 in the distal end and (ii) directing fluid out of the proximally-angled sideholes 42 in the wall of the catheter. The elastic opening 44, however, only increases in diameter as the pressure of fluid increases within the catheter, thus permitting fluid to flow out opening 44 at very high velocities. The *Savage et al.* catheter thus poses a high risk of dissection of tissue and dislodgement of plaque from the vessel walls. In claims 1, 29 and 70, in contrast, the size of the opening decreases as the pressure increases within the tip/restrictor. *Savage et al.* thus teaches the opposite of Applicants' claims in this respect.

For these reasons, Applicants respectfully submit that the combined teachings of the *Lindsay* and *Stevens et al.* patents and the *Savage et al.* publication would not yield the catheter of claims 1, 29 or 70 or their respective dependents. Withdrawal of these rejections is therefore requested.

VII. Various Dependent Claims Stand Rejected Under 35 U.S.C. §103(a)

In sections 47-70 of the Office Action, several dependent clams stand rejected under 35 U.S.C. §103(a) as being unpatentable over various combinations of the prior art of record.

By virtue of their dependency on the independent claims for which arguments for patentability and/or amendments have been made above, the dependent claims are believed to be patentable over the prior art. Applicants therefore respectfully request reconsideration and withdrawal of the 35 U.S.C. §103(a) rejections of all pending claims.

Lastly, although various claims have been amended or canceled herein, Applicant wishes to point out that such revisions are not meant to be construed as an admission of unpatentability of the subject matter recited in earlier versions of the claims. Instead, such revisions should be considered as having been made only to expedite prosecution of the application. They should not be considered as a

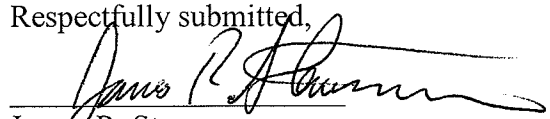
surrender of the right to pursue any subject matter disclosed in the present application or in any continuation or divisional application based thereon that may be filed in the future.

CONCLUSION

Before entry of this *Amendment And Response*, the present application had one hundred twenty one (121) claims, eight (8) of which independent, inclusive of thirty eight (38) withdrawn claims. Upon entry of this *Amendment And Response*, the application will contain one hundred fifteen (115) claims, six (6) of which independent, inclusive of thirty eight (38) withdrawn claims. Applicant previously paid for one hundred twenty one (121) claims total, eight (8) of which independent.

If the Examiner has any questions about this *Amendment And Response*, he is invited to call the undersigned at the number listed below.

Respectfully submitted,



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